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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,146	12/04/2003	Timothy A. Ringeisen	KN P 0146	1356
42016 7590 06/18/2009 KENSEY NASH CORPORATION 735 PENNSYLVANIA DRIVE EXTON, PA 19341				
EXAMINER				
ROGERS, JAMES WILLIAM				
ART UNIT		PAPER NUMBER		
1618				
MAIL DATE		DELIVERY MODE		
06/18/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/729,146

Applicant(s)

RINGEISEN ET AL.

Examiner

JAMES W. ROGERS

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-26, 28-33, 36-50, 52-69, 71-73, 75-87, 90-93 and 95 is/are pending in the application.
- 4a) Of the above claim(s) 66-69, 71-73, 91 and 92 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-26, 28-33, 36-50, 52-65, 75-87, 90, 93 and 95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-846)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/08/2009 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-26,28-30,36-38,42-50,52-65,75-79 and 95 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically claims 22 and 39 which all other claims rejected above depend upon recite "about 0.2 ton per square inch" and claim 22 also recites "about 100 tons per square inch", there is no support within the specification for these limitations. While the paragraph bridging pages 14 and 15 within applicant's specification does recite that the force is applied from 0.01 to 100 tons/square inch, preferably 0.2 to 2.0 tons/square

inch, this recitation does not support the broader limitation of **about 0.2 to about 100** tons/square inch. Note that applicants are clearly narrowing their described in the specification two ways, firstly they are mixing the upper and lower limits from two different recited ranges, 0.01 to 100 tons/square inch and 0.2 to 2.0 tons/square inch and secondly the term "about" broadens the scope of the upper and lower limit to include values slightly below or above 0.2 and 100 tons/square inch.

Claims 22-26,28-33,36-41,75-77,80-81,84,87, 90, 93 and 95 are rejected under 35 U.S.C. 102(b) as being anticipated by Stone (US 5,158,574), as evidenced by Tokyo et al. (US 3,616,205), for the reasons set forth in the previous office actions filed 05/09/2008 and 12/04/2008.

Claims 22-26,28-30,36-38,42-45,47-48,52-65,75-84,87,90,93 and 95 are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al. (US 2002/0127270), as evidenced by Tokyo et al. (US 3,616,205), for the reasons set forth in the previous office actions filed 05/09/2008 and 12/04/2008.

Claims 22-26,28-33,36-50,52-65,75-87,90,93 and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (US 5,158,574), as evidenced by Tokyo et al. (US 3,616,205) in view of Li et al. (US 2002/0127270) and in further view of Haldimann (US 6,428,576 B1, disclosed previously), for the reasons set forth in the previous office actions filed 05/09/2008 and 12/04/2008.

Applicant's arguments filed 05/08/2009 have been fully considered but they are not persuasive.

Applicants assert that none of the references above disclose their newly amended claims that require an implantable device containing a lubricant comprising a soluble collagen.

The relevance of these assertions is unclear. The examiner does not find the new limitation "soluble collagen" to be particularly limiting since it doesn't set forth any conditions in which the collagen is solubilized nor is such a term defined within the specification. Thus essentially any collagen could read on soluble collagen, since the conditions used to solubilize the collagen would be limitless (high temperature, use of pepsin, proteolytic enzymes, under acidic conditions ect). Both Stone and Li teach the use of collagen along with other fibers for making the implants, thus applicants have not amended their claims in such a way to preclude either the Stone or Li references. As evidence the examiner relies upon the description within Tokyo, who clearly describes methods to solubilize even so called insoluble collagens. See entire description within. Thus the examiner considers any collagen as being capable of being solubilized depending upon the conditions used.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618